TCT-272

Durable Effectiveness of the Taxus Liberté Stent: Final 5-year Follow-up of the Taxus Atlas Trial

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Background: The TAXUS Liberté stent (Boston Scientific, Natick, MA, USA) has thinner struts and more uniform vessel scaffolding than the earlier TAXUS Express platform. The multicenter TAXUS ATLAS trial demonstrated the non-inferiority of TAXUS Liberté versus TAXUS Express for 9-month target vessel revascularization (TVR). Whether TAXUS Liberté would remain safe and effective at the final 5-year trial endpoint was unknown.
Methods: The TAXUS ATLAS trial was a prospective, single-arm study comparing TAXUS Liberté (N=871) to historic, lesion-matched TAXUS Express controls (N=991) from TAXUS IV and V. Patients with single, *de novo* coronary lesions 10 - 28 mm in length and in vessels 2.5 - 4.0 mm in diameter (visual estimate) were enrolled. The trial was fully monitored and adjudicated by an independent clinical events committee.
Results: Non-angiographic baseline patient characteristics were similar between the groups, but quantitative coronary angiography determined that TAXUS Liberté patients were more likely to have higher percent diameter stenosis (69.1% vs 66.8%, p<0.001), longer lesions (14.76 mm vs 13.60 mm, p<0.001), tortuous vessels (13.1% vs 8.4%, p=0.001), calcification (29.8% vs 23.1%, p=0.001), and ACC/AHA Type B2 or C lesions (75.5% vs 61.2%, p<0.001) than TAXUS Express patients. Despite the differences in lesion complexity, TAXUS Liberté compared with TAXUS Express resulted in a similar rate of major adverse cardiac events (26.2% vs 27.1%, p=0.70) at 5-year follow-up. The effectiveness measures of TVR (18.9% vs 20.0%, p=0.54) and target lesion revascularization (11.0% vs 11.5%, p=0.72) were comparable and sustained through 5 years between TAXUS Liberté and TAXUS Express. Through 5 years, safety measures including all-cause death (8.4% vs 9.8%, p=0.30), cardiac death (5.1% vs 4.4%, p=0.49) and myocardial infarction (7.6% vs 8.4%, p=0.57) remained low and comparable between the TAXUS Liberté and TAXUS Express groups. Stent thrombosis (ST) rates per protocol definition at 5 yrs were similar between TAXUS Liberté and TAXUS Express (2.3% vs 2.0%, p=0.66).
Conclusions: Despite the increased lesion complexity for the TAXUS Liberté group, clinical outcomes at 5 year post stent implantation were similar for the TAXUS Liberté and TAXUS Express stents. TAXUS Liberté has demonstrated through 5 years a durable effectiveness in reducing restenosis while maintaining safety compared with TAXUS Express.

TCT-273

Incidence, Predictors and Clinical Impact of Periprocedural Myocardial Following Drug-Eluting Stent Implantation in Complex Patients from Daily Clinical Practice

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Background: Periprocedural myocardial infarction (PMI) is a relatively common complication (2-12%) following percutaneous interventions; however, its clinical impact remains controversial.
Methods: From May/02-Mar/09, 2,855 unselected pts undergoing drug-eluting stent implantation at a single center were prospectively enrolled in the DESIRE registry. PMI was defined as EKG changes and/or CKMB rise >3 times the upper normal limit measured up to 48 hours post index procedure. Clinical follow-up (FU) up to 8 years was performed in 98%. We report the results in pts with minimum of 1 year FU.
Results: Mean age was 63.9 years, 29% had diabetes, and 22% previous MI. LAD was treated in 43%, 62% had multivessel disease (MVD), 6% saphenous vein grafts (SVG), and 66% of lesions (n=4,142) were classified as type B2/C. During procedure, 6% received IIb/IIIa inhibitors, 51% had predilatation, 1.6 stents were implanted per pt, and angiographic success was achieved in 99%. PMI occurred in 3.4% of pts; however, there was no in-hospital cardiac death associated to this event. At late FU (median 3.8 years), pts with PMI had 5.2% cardiac death vs. 3.1% in pts without PMI (p=0.15). Regarding stent thrombosis (ST), pts with PMI had increased overall ST rate (3.1% vs. 1.6%, p=0.13) which was mainly due to a significant increase in subacute (<30 days) ST (2.1% vs. 0.3%, p=0.02). Independent predictors of PMI were: *de novo* lesions (HR 3.41, p=0.038), SVG (HR 3.21, p<0.001), male gender (HR 2.10, p=0.018), reference diameter (HR 1.65, p<0.001), lesion predilatation (HR 1.61, p=0.003), and renal insufficiency (HR 1.85, p=0.021) and MVD (HR 1.59, p=0.044).
Conclusions: In this subanalysis of the DESIRE Registry including complex real-world pts, PMI occurred in 3.4% of pts and was significantly associated with de novo lesions, SVG, male gender, large vessels, predilatation, renal insufficiency, and MVD. At late FU, pts with PMI had higher rates of subacute ST (p=0.02), and trends towards increased cardiac death and overall ST compared to pts without PMI.

TCT-274

The Use of a Different Drug Eluting Stent for the Treatment of Drug Eluting Stent Restenosis is Associated with a Lower Revascuarization Rate

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Background: Currently, little data are available on optimal treatment of drug-eluting stent (DES) restenosis (ISR). The absence of clear recommendations in the guidelines makes DES ISR treatment one of the most challenging situations in interventional cardiology.
Objectives: To compare the outcomes of a same versus a different DES implantation strategy for the treatment of DES ISR.
Methods: We identified all cases of DES ISR that were treated with a second DES between Jan/2004 and Jan/2009. The lesions were divided into those receiving the same DES as the one that restenosed and those treated with a different DES. The end points analyzed were repeat target lesion revascularization (TLR) at 6 and 12 months.
Results: We included 131 lesions (115 patients) that were treated initially with Cypher® in 61%, Taxus® in 33.6%, Xience V® in 2.3% and Endeavor® in 3.1%. The same DES was implanted in 39 lesions (30%) and a different DES in 92 lesions (70%). ISR pattern of the first DES was focal in 59.5%, diffuse in 22.1%, proliferative in 7.6% and occlusive in 10.7%. In our series, TLR at 6 months occurred in 21.2% of cases treated with the same DES and 1.2% of those treated with a different DES (p<0.001). TLR at 12 months was 42% vs 4.5% respectively (p<0.001). Multivariate analysis found a same DES strategy to be a significant predictor of TLR at 6 months (OR= 24.06, 95% CI [1.8-320]; p=0.016) and 12 months (OR= 31.4, 95% CI [4.2-231]; p=0.001).
Conclusions: According to our results, implanting a DES type other than the original one should be recommended in case of DES ISR since it is associated with lower TLR at 6 and 12 months.

TCT-275

Drug-eluting Stents And Post-PCI Angina At One Year: Do Label Indications Matter?

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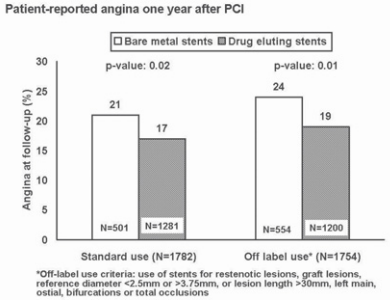
Background: While off-label use of drug-eluting (DES) stents has been linked to adverse clinical outcomes in observational studies, little is known about the impact of DES vs. bare metal stents (BMS) on patient-reported symptoms following PCI.
Methods: We compared 1-yr angina status by stent type among 3536 patients enrolled in the National Heart, Lung and Blood Institute-sponsored Dynamic Registry (BMS only: wave 2, 1999; DES only: waves 4, 5, 2004-6). Patients who received both stent types in waves 4 and 5 were excluded. Off-label use included restenotic, ostial, bifurcation, left main or graft lesions, total occlusions, vessel diameter <2.5mm or >3.75mm or lesion length >30mm.
Results: Off-label use occurred in 53% of the patients with BMS (N=1055) and 48% of patients with DES (N=2481). Overall, fewer patients receiving DES vs. BMS reported angina one year after PCI (18% vs. 23%, p <0.001); similar trends were seen in both standard and off-label groups (**Figure**). Hierarchical logistic regression models adjusting for age, sex, race, smoking status, clinical comorbidities, prior revascularization and primary reason for PCI including angina status showed a significantly lower risk of angina with both standard [odds ratio (95% CI): 0.75 (0.57-1.0); p:0.05] and off-label [OR(95% CI): 0.74 (0.56-0.98); p:0.03] DES use. These improved symptoms were observed despite the greater need for repeat interventions with BMS (BMS vs. DES: standard use- 12 vs. 6%, off-label use- 18 vs. 12%; p<0.01 for both).



Conclusion: In this large multicenter registry of unselected PCI patients, both standard and off-label DES use are associated with better angina status after PCI as compared with BMS use. These data highlight the spectrum of benefits with DES use and extend the documented *clinical effectiveness* of these stents to show favorable impact on *patient-centered outcomes.*

TCT-276

Safety and Efficacy of Everolimus-Eluting Stents Compared to Paclitaxel-Eluting Stents: A Meta-Analysis of 4 Trials

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Background: Drug-eluting stents (DES) significantly reduce the incidence of in-stent restenosis and the need for repeat revascularization compared to bare-metal stents. Due to improved stent design, next-generation DES may be superior to first-generation DES in terms of safety and efficacy.
Methods: We performed a random-effects meta-analysis from the four randomized clinical trials (SPIRIT II, III, and IV, and COMPARE) which compared the second generation XIENCE V/PROMUS everolimus-eluting stent (EES) with the first generation TAXUS Express/Liberté paclitaxel-eluting stent (PES) for which one year results are available. Endpoints were: all-cause death, myocardial infarction (MI), target lesion revascularization (TLR), and ARC definite or probable stent thrombosis.
Results: In total, 4,194 patients received EES and 2,489 patients received PES. At one year, no significant difference was observed in the incidence of all-cause death between the groups (Figure). However, patients treated with EES compared with PES had significantly less MI (risk ratio [RR] 0.57, p<0.01), TLR (RR 0.49, p<0.01), and stent thrombosis (RR 0.36, p=0.02). There was no heterogeneity in the results according to the TAXUS Express vs. Liberté platforms.

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